

**U.S. Department of Energy
Guidance Document**

**Development of
Risk-based
End State Visions**

X-XX-03

Executive Summary

This guidance supports the implementation of DOE Policy XXX, *Cleanup Driven by Risk-based End States* dated x-xx-03. The Department's intent is to "do it right the first time." The Department must correct a cleanup process based on multiple interim steps that lead to un-defined end states and cleanup remedies that either don't meet the goal, or unnecessarily exceed it.

This guidance recognizes that implementation of Policy XXX may need to occur in phases. The Department recognizes that sites are subject to different time-constraints and/or regulatory pressures. These constraints include commitments embedded in existing site-specific regulatory agreements, that may affect the time frames by which each site can develop, and implement, risk-based end state visions.

This guidance contains:

- a description of roles and responsibilities;
- schedule requirements
- the guiding principles as provided in the draft policy;
- strategic considerations;
- a set of considerations, or process steps;
- a description of the scope and content of a risk-based, end state; and,
- [the final guidance will include] a discussion of tools that are currently available to facilitate the definition of risk-based end states for each site.

Following the development of risk-based end state visions, sites will need to revise their baselines and Performance Management Plans (PMP) to accurately reflect the activities that will ensure achievement of the site vision.

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Guidance for the Development of Risk-based End State Visions

1.0 Introduction

DOE Policy XXX states that cleanup at a site should be driven by a risk-based end state vision. It is the Department's goal to have the site end state vision supported by the site regulators and stakeholders within the time frames outlined in this guidance. The Department recognizes that Closure Sites have a more time-critical need to define and achieve these end state visions. This document provides guidance on what a vision statement is, and how it should guide risk-based cleanup decisions. The U. S. Environmental Protection Agency and/or States under CERCLA and/or RCRA regulate site cleanup programs. Site vision statements should be supported by the regulatory community, the local community, Tribal Nations, and affected stakeholders.

An end-state vision is the agreed-to vision for land use at the end of cleanup. Factors affecting this vision include the Department's mission requirements for the site and the land use in the surrounding area. The land use includes property that the Department may continue to own (e.g., at a continuing mission site), property that is managed by another Federal agency (e.g., U.S. Fish & Wildlife Service), and property that is privately-owned and borders the DOE property undergoing cleanup.

The end state vision will the Department, its regulators and stakeholders to make decisions based on an end state for the cleanup. Knowing the end state will enable the site to know what is required to ensure adequate protection of human health and the environment for the intended land use. Sites may determine there is more than one land use for the property, as a whole. In such cases, it will be important to determine the boundaries of these land uses, so that points of compliance can be determined and that actions taken by the Department are protective of human health and the environment at those points of compliance.

It is important for sites to consistently apply the same definition of "risk" during the development of risk-based end state visions. For purposes of implementing Policy XXX and this guidance, the term means the risk to human health and the environment after remediation is complete. There are three primary components that must be considered in the analysis of end state risk: the expected land use, the remaining hazards, and the primary receptors.

2.0 Roles and Responsibilities

Assistant Secretary for Environmental Management (EM-1): Monitor site compliance with Policy # XXX and this guidance. Act as DOE Advocate of Policy # XXX and this guidance, including coordination with U.S. Environmental Protection Agency, national stakeholder groups, tribal nations, other Federal agencies, and other interested parties. Provide necessary resources to sites to implement Policy # XXX and this guidance.

Field Office Managers: Implement Policy # XXX and ensure that all sites under his/her purview follow the guiding principles, process requirements and schedules outlined in this guidance. Provide necessary resources to subsidiary sites to implement Policy #XXX and this guidance.

Site Managers: Implement Policy # XXX and follow the guiding principles and process requirements outlined in this guidance to define and achieve a risk-based end state vision, and meet all schedule requirements outlined in this guidance. Plan for and request the necessary resources to implement Policy # XXX and this guidance.

3.0 Schedule Requirements

Sites provide their draft End State Visions to regulators and stakeholders for review and comment by June 1, 2003.

Sites should receive endorsement of End State Visions from regulators and stakeholders by September 1, 2003.

Sites shall revise their cleanup baselines and associated Performance Management Plans (PMP) to be in alignment with their risk-based, end states by March 31, 2004.

4.0 Guiding Principles

As outlined in DOE Policy XXX, efforts to develop and achieve risk-based end states must be based on the following principles:

- C The Department will comply with the requirements of the nation's environmental laws and regulations. However, the requirement to develop and achieve risk-based end states will drive the Department's compliance strategy.
- C End states, including the selected remedies, must be based on an integrated site-wide perspective (including the current and future use of surrounding land), rather than on isolated operable units or release sites.
- C End states must be focused on protecting the relevant receptors based on the intended land use. Sites must document the final anticipated risk-based condition that drive a cleanup decision or activity.
- C Sites must consider the interim risks to the public, workers, and the environment in the selection of actions required to achieve risk-based, end states. Ecosystem health should not be endangered nor should workers be put at risk by requiring them to take actions that result in little or no reduction in risk to the public or the environment.
- C Where contaminants are expected to persist but can be isolated, risk concepts should include effective and transparent institutional controls to maintain isolation. Long term monitoring and surveillance methods must be designed to assure that the contaminants remain sequestered and human health and the environment are protected.
- C Stakeholders and regulators must be consulted in the actions needed to develop and achieve risk-based, end-states.

- C End states must address how we are to manage the impacts of future risks and vulnerabilities, including the creation of contingency plans in the event that site conditions change after clean up is completed.

5.0 Strategic Considerations

The Department's strategy for implementing Policy # XXX and this guidance will depend on the stage that cleanup is in for each particular site. For sites that have not yet established future land use, or cleanup criteria suitable for that land use, discussions with the regulatory agencies should begin as soon as possible. For those sites that are further along in the process, for example, all the Records of Decisions and cleanup criteria have been negotiated and approved by the DOE, EPA, and State, more internal planning may need to be completed before the regulatory agencies or stakeholders are approached.

The steps in this DOE-internal planning should include:

1. An initial evaluation of what new cleanup criteria could be established that are based on a "pure" risk-based end state;
2. The cost savings resulting from any changes to cleanup criteria, renegotiation of regulatory agreements;
3. Legal options and pathways for any change;
4. Schedule constraints (for example, can such changes be made in a timely manner while still meeting legally-required milestones already agreed to?); and
5. The "climate" for changes, with the regulatory agencies, stakeholders, and Tribal governments, and a plan to successfully re-negotiate the original cleanup criteria.

If an internal plan is developed that considers the above points and demonstrates that significant benefits can be gained by the Department as well as the communities most affected by DOE's historical operations and ensuing EM cleanup, then the likelihood of successful implementation of Policy# XXX will be greatly increased.

Once a risk-based end state vision has been established, a strategy for reaching that end state can be created. Sites will need to assess if site conditions have been adequately characterized, in order to clearly define the end state goals. This characterization must include a validated site conceptual model that defines what data needs exist. The strategy will determine the extent of active remediation required, versus using barriers or contaminant containment efforts or other engineered and/or institutional controls.

The strategy also needs to meet all applicable regulatory requirements. At some sites, there may be more than one regulation driving the cleanup (e.g., CERCLA, RCRA, AEA, TSCA). At an NPL site, for example, Section 121(d) of CERCLA requires compliance with site-specific Applicable or Relevant and Appropriate Requirements (ARARs), unless the action qualifies

under a limited list of ARAR waivers. NPL sites are encouraged to take advantage of the waivers process in defining a risk-based end state. Other cleanup authorities may also have flexibility similar to the ARAR waiver process. Sites may also need to renegotiate Federal Facility Agreements or other regulatory agreements, in order to achieve the new end state.

Finally, consideration of the long-term cost of stewardship requirements for the end-state goals must be incorporated in the strategy. Sites should document the risk-based considerations driving the requirement for all cleanup activities.

6.0 End State Vision Considerations

Nine considerations to be discussed during the preparation of a site's risk-based end state vision.

1. Life-cycle cost must be considered.

Each site must possess the ability to adequately characterize the problem, forecast remediation achievements, link these achievements to future use, and forecast the engineering and/or institutional controls needed to both secure the blocked pathway and to monitor performance of the remedy. "Trade-offs" between characterization, remediation, future monitoring and any institutional or engineered controls is a necessary part of end state definition and remedy design.

2. The "end state" begins when a steady state in the remedy is achieved.

For the purposes of the end state vision document, the end state begins when the remedy is proven to be operating as designed. For example, the end state can be achieved once a ground water pump and treat system is operational. It does not mean that the final objective of the pump and treat system is attained and the system is dismantled.

3. A focus on site restoration, property revitalization and reuse.

The use of a reasonable land use scenario in setting cleanup standards is expected. Land use considerations include: the continued DOE mission on site; transfer of land ownership to another Federal agency, State or Local government; and recreational use.

4. Minimize the creation of new waste disposal sites.

If it is not technically feasible to clean a site to an unrestricted or recreational use standard, then the site should not design a remedy that involves the transfer of waste materials to an otherwise "clean" site. Transfer of waste materials to an existing waste disposal site is acceptable, however, the site should first consider whether it may be best to simply cap and leave wastes in-place, particularly if technological limitations prevent complete removal of all wastes.

5. Use a risk-based site conceptual model that includes land use considerations.

The site conceptual model must take into consideration all sources of contamination, all release mechanisms (e.g., volatilization, leaching), all exposure points (e.g., air, groundwater), all

exposure routes (e.g., inhalation, dermal contact), and all human receptors (e.g., site worker and member of public) as well as environmental receptors (e.g., endangered species, ecologically significant biota) or other considerations (e.g., cultural resources, historically significant properties). During final development and acceptance of the end state vision, sites should consider the relevant pathways and receptors when analyzing risk to human health and the environment. The site conceptual model must also include a vision of the contamination footprint, after remediation is complete, as well as the proposed land use.

6. A regulatory strategy that allows completion of the cleanup mission.

The regulatory strategy must allow DOE to articulate when the end state begins and when the remedy is complete. The RCRA and CERCLA regulations clearly state which documents are enforceable, however, there may be unenforceable documents (e.g., plans) - that constitute an important element of the exit strategy.

7. Use decision analysis and logic tools that are relevant and appropriate.

Sites should conduct site-wide risk evaluations using, as appropriate, decision/risk analysis, visualization, and logic tools that promote understanding of alternative risk-based end states that protect human health and the environment. These evaluations should include, at a minimum, the following attributes: present and future hazards (e.g., surface and subsurface contamination footprints); institutional controls (e.g. land use); and credible pathways of exposure (i.e., exposure assessment). The evaluations should include groundwater and ecological considerations related to postulated end state activities. Sites should use these human health and environmental risk assessment tools in conjunction with broader “systems” evaluations, such as short-term worker and ecological exposure, as well as cost impacts, to compare the impacts and benefits of alternative end states.

8. Establish an integrated soil and groundwater compliance strategy.

The end state vision may consider a property transfer in its entirety, or the property may be divided for different land use scenarios. Depending on the situation, a single or multiple groundwater points of compliance may be established as a part of the cleanup strategy. In such cases, it is vital that the soil compliance strategy be considered in conjunction with the groundwater compliance strategy. Furthermore, contingency plans should be designed along with the integrated compliance strategy, in the event that future site conditions change unexpectedly.

9. Integrate monitoring and surveillance plans with the end state vision.

As a part of the long term management plan for cleanup sites, monitoring and surveillance plans must be designed to effectively support the end state vision. Stakeholders, regulators, local communities and future property owners must be well informed of any residual contaminant risks. Monitoring data accumulated in accordance with an agreed-to schedule gives all parties full disclosure of site conditions beyond just the cleanup activities.

7.0 Scope and Content

This section describes the scope and content of the document that contains the risk-based end state vision. First, it is important to clearly state what the vision document is not.

The vision document is not:

- a “plan”, per se, and will not prescribe “how” to achieve the site-specific risk-based end states. The vision document describes the end state of the site when the risk-based end state cleanup is completed.
- a document to present every details of remaining hazards (every isotope), controls (e.g., location of every single well) or every facility in place. It needs to show a comprehensive end state picture but not necessary a detailed one.
- a budget or baseline document. Upon completion of the vision document, each site will be required to update site-specific baseline and/or Program Management Plan (PMP) to reflect the risk-based end state vision document.
- a regulatory document. Upon completion of the vision document, each site may be required to revisit current regulatory agreements/documents (such as Federal Facility Agreements) and compliance agreements. Each site will work with local regulators and stakeholders to update the regulatory and compliance agreements to reflect the risk-based end state vision of the site.

The vision document should:

- be consistent with the *Cleanup Driven by Risk-based End State* policy (dated March 30, 2003) and the contents of this guidance document (dated xx);
- contain discussions on the remaining hazards in terms of risks from the contaminants, risks to receptors, and measures undertaken to protect the environment and human health;
- contain maps, drawings, and other data points to communicate what the end state looks like. Any tools used to depict the end state must clearly articulate remaining contaminants, any protective measures undertaken, and remaining operating systems;
- contain discussion of land use on and around the site. It should contain discussion of expected use when cleanup is completed;
- 10-40 pages¹ in length depending on the complexity of the sites;
- contain discussion of potential issues associated with achieving the discussed end states; and

¹ The length of document is provided only as a reference only. It is not a requirement.

- contain a bibliography with appropriate references.

The following outline is recommended. It is recognized that there will sites will require some degree of flexibility to reflect the current status of the site.

Executive Summary

Introduction – Discuss outline of the document and other introductory remarks

Site's Risk-based End State Description - describe the site's end state. Include high level maps and drawings as appropriate.

- Remaining Hazards: ground water status, facilities, waste remaining (e.g., disposal cells, capped areas), soil condition, and surface water/sediment
- Protective Measures in Place: discussion of institutional and engineered controls in place including operating systems remain: ground water, facilities, remaining Wastes (e.g., disposal cells, capped areas), soil conditions, surface water/sediment.
- Land Use and Receptors - expected land use and receptors on and around the site (when cleanup is completed), and current land use around the site.

Current and Expected Roles and Responsibility

Issues

8.0 Tools

Note: This section is under development and will be provided with the final guidance document.